



L 954716439 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 10118.00011

PATENT

RECEIVED

MAY 27 2003

TECHNOLOGY CENTER R3700

In the Application of:

Huakun Xu, et al.

Serial No.: 10/086,484

Filed: March 1, 2002

For: Self-Hardening Calcium Phosphate
Materials With High Resistance To
Fracture, Controlled Strength Histories
And Tailored Macropore Formation
Rates

Art Unit 3732

RECEIVED

MAY 29 2003

TC 1700

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. SECTIONS 1.97 AND 1.98**

Mail Stop DD
Commissioner for Patents
P. O. Box 1450
Alexandria, VA, 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Sections 1.97 and 1.98, applicants wish to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. A copy of the references cited below are enclosed. The references are also listed on the enclosed and completed PTO/SB/08A form.

BANNER & WITCOFF, LTD.
Ten South Wacker Drive
Chicago, Illinois 60606
(312) 463-5000

Attorney Docket No. 10118.00011
Serial No. 10/086,484

U.S. Patents

1. U.S. Patent No. 4,512,038, Alexander et al., issued April 23, 1985.
2. U.S. Patent No. 4,655,777, Dunn et al., issued April 7, 1987.
3. U.S. Patent No. 4,963,151, Ducheyne, et al., issued October 16, 1990.
4. U.S. Patent No. 5,181,930, Dumbleton, et al., issued January 26, 1993.
5. U.S. Patent No. 5,192,330, Chang et al., issued March 9, 1993.
6. U.S. Patent No. 5,525,148, Chow et al., issued June 11, 1996.
7. U.S. Patent No. 5,545,254, Chow et al., issued August 13, 1996.
8. U.S. Patent No. 5,556,687, McMillin, issued September 17, 1996.
9. U.S. Patent No. 5,652,056, Pepin, issued July 29, 1997.
10. U.S. Patent No. 5,721,049, Marcolongo et al., issued February 24, 1998.
11. U.S. Patent No. 5,766,618, Laurencin, et al., issued June 16, 1998.
12. U.S. Patent No. 5,976,234, Chow et al., issued November 2, 1999.
13. U.S. Patent No. 5,997,624, Chow et al., issued December 7, 1999.
14. U.S. Patent No. 6,077,989, Kandel, et al., issued June 20, 2000.
15. U.S. Patent No. 6,136,029, Johnson, et al., issued October 24, 2000.
16. U.S. Patent No. 6,207,098, Nakanishi, et al., issued March 27, 2001.
17. U.S. Patent No. 6,214,008, Illi, issued April 10, 2001.
18. U.S. Patent No. 6,281,256, Harris, et al., issued August 28, 2001.
19. U.S. Patent No. 6,281,257, Ma, et al., issued August 28, 2001.
20. U.S. Patent No. 6,287,341, Lee et al., issued September 11, 2001.

Other Documents

21. Brown and Chow, "A New Calcium Phosphate Water Setting Cement", ppg. 352-379 in Brown, *Cements Research Progress*, American Ceramic Society, 1986. —
22. Ginebra et al., "Setting Reaction and Hardening of an Apatitic Calcium Phosphate Cement", *J. Dent. Res.* 76:905-912, 1997. —
23. Constantz et al., "Histological, Chemical and Crystallographic Analysis of Four Calcium Phosphate Cements in Different Rabbit Osseous Sites", *J. Biomed. Mater. Res. [Appl. Biomater.]* 43:451-461, 1998. —
24. Miyamoto et al., "Histological and Compositional Evaluations of Three Types of Calcium Phosphate Cements When Implanted in Subcutaneous Tissue Immediately After Mixing", *Biomed Mater. Res. [Appl. Biomater.]* 48:36-42. —
25. Lee et al., "Alpha-BSM(R): A Biomimetic Bone Substitute and Drug Delivery Vehicle", *Clin. Orthop Rel. Res.* 367:396-405, 1999. —
26. Ishikawa et al., "Reaction of Calcium Phosphate Cements With Different Amounts of Tetracalcium Phosphate and Dicalcium Phosphate Anhydrous", *J. Biomed. Mater. Res.*, 46:504-510, 1999. —
27. Matsuya et al., "Effects of Mixing Ratio and Ph on The Reaction Between $\text{Ca}_4[\text{PO}_4]_2\text{O}$ and CaHPO_4 ", *J. Mater. Sci.: Mater. in Med.* 11:305-311, 2000. —
28. Takagi et al., "Morphological and Phase Characterizations of Retrieved Calcium Phosphate Cement Implants", *J. Biomed Mater. Res. [Appl. Biomater.]* 58:36-41, 2001. —

29. Shindo et al., "Facial Skeletal Augmentation Using Hydroxyapatite Cement", *Arch. Otolaryngol. Head Neck Surg.* 119:185-190, 1993. ✓
30. Sugawara et al., "In Vitro Evaluation of the Sealing Ability of a Calcium Phosphate Cement When Used as a Root Canal Sealer-Filler", *J. Endodont.*, 16: 162-165, 1990.
31. Chohayeb et al., "Evaluation of Calcium Phosphate as a Root Canal Sealer-Filler Material", *J. Endodont.* 13:384-387, 1987. ✓
32. Costantino et al., "Experimental Hydroxyapatite Cement Cranioplasty", *Plast. Reconstr. Surg.* 90:174-191, 1992. ✓
33. Friedman et al., "BoneSource™ Hydroxyapatite Cement: A Novel Biomaterial For Craniofacial Skeletal Tissue Engineering and Reconstruction", *J. Biomed. Mater. Res. [appl. Biomater]* 43:428-432, 1998. ✓
34. LeGeros, "Biodegradation and Bioresorption of Calcium Phosphate Ceramics", *Clin. Mater.* 14:65-88, 1993. ✓
35. Simske et al., "Porous Materials for Bone Engineering", *Mater. Sci. Forum* 250:151-182, 1997. ✓
36. Suchanek et al., "Processing and Properties of Hydroxyapatite-Based Biomaterials For Use as Hard Tissue Replacement Implants", *J. Mater. Sci* 13:94-117, 1998. ✓
37. Xu et al., "Strong and Macroporous Calcium Phosphate Cement: Effects of Porosity and Fiber Reinforcement on Mechanical Properties", *J. Biomed. Mater. Res.* 57:457-466, 2001. ✓
38. Xu et al., "Reinforcement of a Self-Setting Calcium Phosphate Cement With Different Fibers", *J. Biomed. Mater. Res.* 52:107-114, 2000. ✓

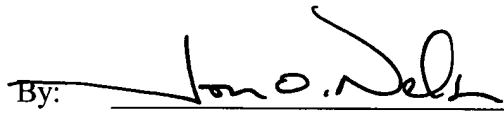
39. Xu et al., "Effects of Fiber Length and Volume Fraction on the Reinforcement of Calcium Phosphate Cement", *J. Mater. Sci; Mater. In Med* 12:57-65, 2001. ✓
40. Von Gonetn et al., "Load-Bearing Behavior of a Simulated Craniofacial Structure Fabricated From a Hydroxyapatite Cement and Bioresorbable Fiber-Mesh", *J. Mater. Sci.: Mater. In Med* 11:95-100, 2000. ✓
41. Takagi et al., "Formation of Macropores in Calcium Phosphate Cement Implants", *J. Mater. Sci.: Mater. In Med.* 12:135-139, 2001. ✓
42. Chow, "Calcium Phosphate Cements" Chemistry, Properties, and Application", *Mat. Res. Symp. Proc.* 599:27-37, 2000. ✓
43. Xu et al., "Calcium Phosphate Cement Containing Resorbable Fibers For Short-Term Reinforcement and Macroporosity", *Biomaterials* 23:193-202, 2002. ✓
44. Chow et al., "Calcium Phosphate Cements", *Cements Research Progress*, ppg. 215-238. ✓
45. Chang et al., "Osteoconduction at Porous Hydroxyapatite With Various Pore Configurations", *Biomaterials* 21:1291-1298, 2000. ✓
46. Matsuya et al., "Effect of Fluoride on Apatite Formation From $\text{Ca}_4(\text{PO}_4)_2\text{O}$ in 0.1 mol L^{-1} KH_2PO_4 ", *J. Mater. Sci.: Mater. In Med.* 9:325-331, 1998.

47. Shors et al., "Porous Hydroxyapatite", *An Introduction to Bioceramics*, ppg. 181-198 in Hency et al., *An Introduction to Bioceramics*, World Sci. Pub., NJ, 1993.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Date: May 16, 2003

By: 
Jon O. Nelson
Reg. No. 24,566